K130494

unitron.

MAY 07 2013

5. 510(k) Summary

Submitter: Unitron Hearing Inc.
14755 27th Avenue North,
Plymouth MN 55447
Phone (763) 744- 3300
Fax (763) 557-8828

Contact Person: Jim Reiter,
Quality Assurance Manager
Unitron Hearing Inc.
14755 27th Avenue North,
Plymouth MN 55447
Phone (763) 744-3463
Fax (763) 557-8828

Date Prepared: 10-January-2013

Device Name: Unitron Tinnitus Masker feature

Device Class: Class II

Classification Name: Tinnitus Masker

Product Code: KLW

Regulation Number: 21 CFR §874.3400 *Tinnitus Masker*

Predicate Device(s): K110932, GN ReSound Tinnitus Sound Generator Module

Description of Device: Unitron's Tinnitus Masker feature is a noise generator available as an option, in Unitron Era hearing aid platforms providing a sound enrichment source, to provide stimulation to the auditory system, as part of a comprehensive tinnitus management program that works to help distract the wearer's attention from the sound of their tinnitus.

Indications for Use: Unitron's tinnitus masker is a broadband sound generator available in Unitron Era hearing aid platforms. It provides a means of sound enrichment therapy that can be used as part of a personalized tinnitus management program to provide temporary relief from tinnitus.

Tinnitus masker is intended for adults 18 years of age or older who have both hearing loss and tinnitus. The tinnitus masker within the air conduction hearing instrument is fitted by a hearing health care professional familiar with diagnosis and management of tinnitus.

The underlying principle of sound enrichment is to provide supplementary noise stimulation which can help defocus your attention from your tinnitus and avoid negative reactions. Sound enrichment, coupled with instructional counseling, is an established approach to managing tinnitus.

Substantial Equivalence: Comparison to the Predicate Device indicated above shows the Tinnitus Masker feature has the same intended use and does not raise additional safety and effectiveness questions.

Technology Characteristics Comparison: Unitron Tinnitus Masker uses the same technology used by the predicate device, sharing the following similarities:

- Similar indications of use, implementation into software, functionality through digital hearing instruments, fitter adjustments to stimulus shaping, maximum output and end user control.

The technology characteristics that differ from the predicate device are:

- Amplitude Modulation.
- Environment Steering (automatic fluctuation of the noise level based upon the environment).

Performance Data: Unitron Hearing Instruments with the tinnitus masker feature and related software have been evaluated in accordance with ANSI S3.22:2009 American National Standard - Specification of Hearing Aid Characteristics, IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance and IEC 60601-1-2 Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.

Conclusion: Based upon similar indications of use and technology characteristics it is concluded to be substantially equivalent to K110932, GN ReSound Tinnitus Sound Generator Module

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 7, 2013

Unitron Hearing, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K130494
Trade/Device Name: Unitron Tinnitus Masker Feature
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: March 19, 2013
Received: March 20, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

unitron

4. Indications for Use

Indication for Use Form

Indications for Use

510(k) Number (if known): K130494

Device Name: Unitron Tinnitus Masker feature

Indications for Use:

Unitron's tinnitus masker is a broadband sound generator available in Unitron Era hearing aid platforms. It provides a means of sound enrichment therapy that can be used as part of a personalized tinnitus management program to provide temporary relief from tinnitus.

Tinnitus masker is intended for adults 18 years of age or older who have both hearing loss and tinnitus. The tinnitus masker within the air conduction hearing instrument is fitted by a hearing health care professional familiar with diagnosis and management of tinnitus.

The underlying principle of sound enrichment is to provide supplementary noise stimulation which can help defocus your attention from your tinnitus and avoid negative reactions. Sound enrichment, coupled with instructional counseling, is an established approach to managing tinnitus.

Prescription Use _X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Srinivas Nandkumar -S